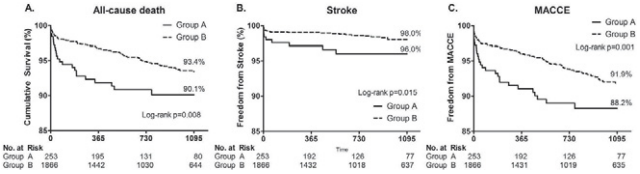
with history of stroke were excluded and total 2,119 patients were analyzed. Ischemia was detected by brain MRA in 253 patients (group A), but not in 1866 patients (group B). Preoperative characteristics, follow-up survival, and cardiac and neurological events were investigated.
Results: The median follow-up period was 2.2 years. Univariate analysis showed that patients in group A (65.4 ± 8.3 years) were older than those in group B (63.0 ± 9.0 years) (p<0.001). Diabetes mellitus was more common in group A (48.6%) than group B (40.9%) (p=0.019). The prevalence of chronic kidney disease was higher in group A (63 patients: 24.9%) compared with group B (324 patients: 17.4%) (p=0.004). The prevalence of peripheral vascular disease was higher in group A (13 patients: 5.1%) than in group B (39 patients: 2.1%) (p = 0.003). Euroscore was higher in group A (4.3 ±2.3) than group B (3.6 ±2.2) (p<0.001). Survival rate was significantly lower (93.4% vs. 90.1%, p = 0.008), and freedom from stroke or major adverse cardiac and cerebrovascular event were significantly lower in group A (98.0% vs. 96.0%, p = 0.015, and 91.9% vs. 88.2%, p = 0.001).



Conclusion: Preexisting ischemic findings on brain MRA in patients who undergoing CABG were related to death, stroke, and major adverse cardiac and cerebrovascular event.

TCT-97

From US Pivotal Study to 1200 Patients on 6 Continents: A Global Perspective on the Endurant Stent Graft

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Background: Endovascular abdominal aortic aneurysm (AAA) has evolved since first being approved in the US in 1999. Outcomes have changed with increased operator experience and the approval of new devices. The Endurant stent graft system (Medtronic, Santa Rosa CA) which was approved in late 2010 is the first next generation device to be commercialized in the US. This device seeks to expand the indications of EVAR in short, angulated necks, as well as, patients with small peripheral access vessels. However, are US pivotal study results indicative of global experience?
Methods: Over 1400 patients have been enrolled in Endurant clinical studies or registries since first in human studies commenced in Europe. The three studies used in this analysis are the Endurant European study which enrolled 80 patients, the US Pivotal study which enrolled 150 patients, and the ENGAGE global registry. Data from the ENGAGE registry includes results from the first 839 patients at 30 days and the first 152 patients at 1 year.
Results: Deployment success was achieved in 99.6% of patients across all studies. In the US Pivotal study there was 0% all-cause mortality at 30 days. In comparison, 30 day all-cause mortality in the EU study and ENGAGE were 2.5% and 0.9% respectively. At 1 year, there were no incidences of Type I/III endoleak, migration, or conversion in either the US Pivotal or the EU study. Similarly, there was a 1% incidence of Type I/III endoleak, no incidence of migration, and a 0.8% incidence of conversion at 1 year in ENGAGE.
Conclusion: Early and midterm outcomes with the Endurant stent graft system in the treatment of AAA are consistent across global studies with high clinical success and low complication rates.

TCT-98

Carotid Artery Revascularization with Distal Protection in High Surgical Risk Patients in Routine Clinical Practice: Results of the CABANA Safety Surveillance Program

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Background: The multicenter, nonrandomized CABANA Study evaluated periprocedural outcomes in high surgical risk patients with carotid artery stenosis treated with the Carotid WALLSTENT plus FilterWire EZ Embolic Protection System (Boston Scientific Corporation, Natick, MA).
Methods: The study enrolled 32.7% symptomatic and 67.3% asymptomatic patients at high risk for carotid endarterectomy (CEA) due to prespecified anatomical criteria and/or medical comorbidities. Study centers were grouped into 1 of 3 tiers based on having high, medium, or low previous carotid artery stenting (CAS) experience while individual operators were grouped by their CAS credential-based study training requirements. Follow-up at 30 days included clinical evaluation and independent neurologic and NIH stroke scale assessments. The primary endpoint was the 30-day composite of major adverse events (MAE), including stroke, death, and myocardial infarction (MI).
Results: Of the 1,097 enrolled patients, technical success was achieved in 1,010 (97.1%); the stroke rate (3.3% [34/1,025]) was a major contributing factor in the overall rate of MAEs (4.6% [47/1,025]). Most strokes were ipsilateral (88.2%) and ischemic (85.3%). The overall mortality was 1.3% (13/1,025); the MI rate was 0.5% (5/1,025). There was no statistically significant association between MAE rates among the 3 center experience tiers (p=0.61) nor among the 3 operator training categories (p=0.26). However, there was a weak trend towards lower MAE rates at centers with greater experience and with operators with more CAS training.
Conclusion: Results demonstrate that CAS with Carotid WALLSTENT and FilterWire EZ is a safe alternative to CEA in high surgical risk patients in routine clinical practice. The study yielded a low composite rate of 30-day MAEs and low individual rates of periprocedural stroke, death, and MI. These rates were consistent across centers with varying levels of CAS experience and operators with varying levels of training on CAS and the Carotid WALLSTENT/FilterWire EZ System.

TCT-99

The SAPPHIRE Worldwide Carotid Artery Stenting with Embolic Protection Study: Outcomes to 1-Year with Over 7,600 Patients

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Background: Carotid artery stenting (CAS) has become a viable alternative to carotid endarterectomy, especially in patients considered high risk for surgery due to medical co-morbidities and anatomically challenging lesions. SAPPHIRE Worldwide is the largest study to date to evaluate long-term outcomes of CAS in patients at high-risk for surgery.
Methods: SAPPHIRE Worldwide is a multicenter, prospective, observational study of CAS performed at multiple centers by physicians with varied experience and utilizing a formal training program. The primary endpoint of major adverse events (MAE) included death, myocardial infarction (MI) and all stroke at 30 days, and ipsilateral stroke was assessed from 31 to 360 days.
Results: To date, over 10,000 patients have been enrolled at 325 participating centers and completed 30-day follow-up. More than 7,600 patients have completed 1-year follow-up evaluation. Thirty percent of patients enrolled were symptomatic, and 46% were over the age of 75 years. At 30-day follow up, the rate of MAE was 4.5% (death 1.3%, MI 0.6%, all stroke 3.3%). Between 30 days and 1 year, 21 additional patients suffered an ipsilateral stroke for a 1-year MAE rate of 6.1%. MAE was significantly lower in patients with asymptomatic vs. symptomatic stenosis (5.1% vs. 8.6%, p<0.0001), and in patients with anatomic high risk factors compared with physiologic factors (4.2% vs.6.9%, p<0.0001). Age < 75 years was also associated with a lower risk of adverse events than seen with older patients (4.5% vs. 8.1%, p<0.0001).
Conclusion: Long-term outcomes with this large cohort of patients undergoing CAS, shows favorable results. The risk of ipsilateral stroke after the periprocedural period was very low at 0.3%.

Imaging

Room 120

Tuesday, November 8, 2011, 10:15 am - 12:25 pm

(Abstract nos 100 - 109)

TCT-100

Neoatherosclerosis and Late Stent Thrombosis After Coronary Bare-Metal Stent Implantation: an Optical Coherence Tomography Study

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Background: Little is available on the neointimal characteristics of the lesions with late stent thrombosis (ST) after bare-metal stenting.
Methods: We evaluated 53 consecutive nonostial stent failure lesions in 53 patients (8 ST and 45 restenoses) by optical coherence tomography.
Results: At the index procedure, 29 patients (55%) were treated for acute coronary syndromes. The median duration of implant was 58.8 months (interquartile range, 8.8 to 117.7 months). Three ST patients (6%) presented with ST-segment elevation myocardial infarction (STEMI), 1 (2%) with non-STEMI, and 4 (8%) with unstable angina. Stent malapposition was detected in 12 lesions (23%). The risk of ST (n = 8) versus restenosis (n = 45) was increased for the patients with low LVEF (mean ± SEM, 47.2 ± 3.2% versus 55.6 ± 1.6%, p = 0.04), high LDL/HDL cholesterol ratio (2.7 ± 0.2

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versus 2.1 ± 0.1, p = 0.05), and for the lesions with short stent length (18.6 ± 1.6 mm versus 23.3 ± 1.4 mm, p = 0.04), with lipid-laden intima (88% versus 44%, p = 0.05), thin-cap fibroatheroma (TCFA)-like intima (75% versus 31%, p = 0.04), and intimal disruption (88% versus 27%, p < 0.01). A multiple logistic regression analysis identified intimal disruption (odds ratio: 19.40, 95% confidence interval: 1.02 to 369.02; p = 0.049) as an independent risk factor for stent thrombosis. The lesions with intimal disruption (n = 19) versus those without (n = 34) expressed a higher incidence of ST (37% versus 3%, p = 0.002), lipid-laden intima (90% versus 29%, p < 0.0001), and TCFA-like intima (84% versus 12%, p < 0.0001). Lesions with stent duration > 2 years (n = 30) versus the others (n = 23) raised the rates of cholesterol crystal (47% versus 0%, p = 0.0001), calcified neointima (47% versus 4%, p = 0.0007), lipid-laden intima (83% versus 9%, p < 0.0001), TCFA-like intima (60% versus 9%, p = 0.0001), and intimal disruption (50% versus 17%, p = 0.01).
Conclusion: Long stent duration leads neointima to be atherosclerotic and disrupted after bare-metal stenting. Late stent thrombosis might be associated with disrupted neotissue.

TCT-101

Positive remodeling is associated with vulnerable coronary plaque components regardless of clinical presentation: virtual histology-intravascular ultrasound analysis

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Background: We used virtual histology-intravascular ultrasound (VH-IVUS) to evaluate the relation between coronary artery remodeling pattern and plaque components in 1,133 patients.
Methods: We divided the patients into two groups according to the remodeling pattern as positive remodeling (PR, remodeling index >1.05) (n=192) and intermediate remodeling (IR, remodeling index ≤1.05 and >0.95)/negative remodeling (NR, remodeling index <0.95) (n=941). VH-IVUS analysis classified the color-coded tissue into four major components: green (fibrotic, FT); yellow-green (fibro-fatty); white (dense calcium); and red (necrotic core, NC). Thin-cap fibroatheroma (TCFA) was defined as focal, NC-rich (≥ 10% of the cross-sectional area) plaques being in contact with the lumen in a plaque burden ≥ 40%.
Results: At the minimum lumen site, PR group had greater plaque plus media area (12.8±4.9 vs. 9.9±3.8 mm2, p<0.001) and greater %NC area (21.7±12.3 vs. 18.2±11.6%, p<0.001) and smaller %FT area (57.0±14.5 vs. 59.4±14.6%, p=0.037) compared with IR/NR group. PR group had greater plaque volume (188±150 vs. 135±130 mm3, p<0.001) and greater %NC volume (19.1±9.6 vs. 16.6±9.2%, p=0.001) and smaller %FT volume (58.3±11.7 vs. 60.6±11.0%, p=0.009) compared with IR/NR group. PR group had more TCFA compared with IR/NR group (21% vs. 13%, p=0.006). Similar findings about plaque components were observed in terms of greater %NC volume and smaller %FT volume in PR group compared with IR/NR group in patients with both acute coronary syndrome and stable angina.
Conclusion: VH-IVUS analysis demonstrates that PR was associated with more vulnerable plaque components compared with IR/NR regardless of their clinical presentation.

TCT-102

Multiple Plaque Rupture, Erosion and Stability as Assessed by Optical Coherence Tomography (OCT), Angioscopy, Intravascular Ultrasound (IVUS) and Coronary Computed Tomographic Angiography (CT-angiography)

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Background: Atherosclerotic plaques associated with acute coronary syndromes (ACS) on histopathological characterisation demonstrate either ruptured fibrous caps (RFC) or intact fibrous caps (IFC). The latter IFC lesions are often referred to as plaque erosions and are responsible for up to one-third of culprit lesions in ACS patients. Invasive and non-invasive imaging modalities including OCT, angioscopy, IVUS and CT-angiography would be useful to disclose the mechanism of ACS.
Methods: While 57 patients with ACS or stable angina consented to multiple invasive and noninvasive imaging procedures, 63 culprit lesions were evaluated by CT-angiography, OCT, angioscopy and IVUS. Whilst intraluminal thrombus was assessed by OCT or angioscopy, culprit lesions were classified further by OCT-based demonstration of fibrous-cap integrity.
Results: Of 38 culprit lesions with ACS, OCT revealed IFC with thrombus (erosion) in 11 (29%) and ruptured fibrous cap in the remaining 27 (71%); all 25 lesions with stable angina had intact-fibrous caps. Fibrous caps were significantly thinner in RFC-ACS than IFC-ACS and stable angina by OCT (45±12μm, 146±49μm, 321±134μm, respectively; p=0.001). CT verified that low-attenuation plaques were more frequently observed in RFC-ACS than IFC-ACS and stable angina (85, 36, 16%; p=0.001) lesions. Similarly, positive remodelling was more predominantly seen in RFC-ACS than IFC-ACS and stable angina (93, 18, 12%; p=0.001). However, none of the specific CT-angiography features clearly distinguished IFC-ACS from stable lesions.
Conclusion: IFC-ACS lesions based on OCT and angioscopic characteristics demonstrated less low attenuation plaque and less positive remodelling than ruptured plaques by CT-angiography. Since there are no unique CT features of non-ruptured culprit lesions to enable their clear distinction from stable lesions, it will be difficult to develop CT-based non-invasive imaging techniques to allow the clear identification of subjects at high risk of developing ACS due to plaque erosion.

TCT-103

Head to head comparison of the neointimal response between metallic and bioresorbable everolimus-eluting scaffolds using optical coherence tomography

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[1]Thoraxcentre, Rotterdam, Netherlands, Rotterdam, Netherlands; [2]Swiss Cardiovascular Center, Bern, Switzerland; [3]Skejby Sygehus, Aarhus, Denmark; [4]Christchurch Hospital, Christchurch, New Zealand; [5]Catharina Ziekenhuis, Eindhoven, Netherlands; [6]St Vicent's Hospital, Melbourne, Australia; [7]Jagiellonian University, Krakow, Poland; [8]Maasstad Ziekenhuis, Rotterdam, Netherlands; [9]Institut cardiovasculaire Paris-Sud, Massy, France; [10]Abbott Vascular, Diegem, Belgium; [11]Auckland City Hospital, Auckland, New Zealand; [12]Cardialysis, Rotterdam, Netherlands

Background: Drug-eluting stents (DES) decrease the risk of restenosis by reducing the neointimal response. However, DES may impair strut coverage and this has been associated with late stent/scaffold thrombosis (ST). Bioresorbable vascular scaffolds (BVS) may overcome the risk of ST when completely resorbed. It is unknown if, during the bioresorption process the neointimal response of the everolimus-BVS (Absorb) differs from that of the metallic everolimus-DES (Xience). The objective of the present study is to compare the neointimal response of Xience and Absorb assessed by optical coherence tomography (OCT) at 1 year.
Methods: A total of 31 and 19 lesions were treated with a single Absorb or Xience scaffolds and imaged with OCT at 1 year. Patients with ST elevation myocardial infarction, chronic total occlusions or requiring overlapped stents were excluded. Neointimal response was assessed as: percentage of uncovered struts, neointimal thickness (NIT), in-stent/scaffold area obstruction and pattern of neointima.
Results: No significant differences in the angiographic lumen loss were seen for the Xience and Absorb (0.18±0.20 mm vs. 0.29±0.36 mm; p=0.42). OCT analysis of 951 cross-sections and 8385 struts demonstrated similar rates of uncovered struts (5.3% Xience vs. 4.5% Absorb; p=0.11), mean NIT (120.6±46.0 μm vs. 136.1±71.4 μm; p=0.82) and in-stent/scaffold area obstruction (12.5±7.1% vs. 13.6±9.7%; p=0.91), respectively. There was a trend of higher heterogenic tissue pattern of neointima (21.1% vs. 6.5%; p=0.12) and less intra-luminal masses (0% vs. 12.9%; p=0.10) with Xience than Absorb.
Conclusion: The Absorb everolimus-BVS demonstrated a similar neointimal response as the Xience everolimus-DES; and the risk of scaffold thrombosis is, with that respect, expected to be comparable to the Xience in the first year. However, the presence of intra-luminal masses at 12 months in a small proportion of patients warranted watchful follow-up of these cases.

TCT-104

The Impact of Intravascular Ultrasound Guidance in Routine Percutaneous Coronary Intervention for Conventional Lesions : Data from the EXCELLENT trial

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Background: Intravascular ultrasound (IVUS) offers tomographic images of coronary artery, helping physicians refine percutaneous coronary intervention (PCI) procedures. However, it is still controversial whether routine use of IVUS in conventional lesions leads to improvement in clinical outcomes after PCI.
Methods: From the EXCELLENT trial, patients were grouped into IVUS-guided versus IVUS-non-guided PCI (619 and 802 patients, respectively). The crude population as well as the propensity score matched pairs were compared with regard to clinical outcome. Thirty-two baseline clinical and angiographic variables were used for propensity scoring.
Results: Baseline characteristics showed younger age and lower incidence of comorbidities in the IVUS-guided PCI group. In 463 matched pairs (926 patients), baseline characteristics were better comparable between the IVUS-guided versus non-guided groups. In terms of procedure profiles, IVUS-guided PCI was associated with longer stenting length, larger stent diameter, and greater number of stents implanted. In the total population, IVUS guidance was associated with a significantly higher risk of periprocedural MI. There were no significant differences in other outcomes. In the matched cohort, IVUS guidance was associated with significantly increased risk of target lesion failure at 1 year (4.3% vs. 2.4%; p=0.047 by conditional logistic